IV. Diagnosis and Treatment of TB Disease in HIV-Negative Individuals

A. Diagnosis

Individuals with suspected TB disease should receive a medical evaluation that includes:

1. Medical and social history (e.g., the TB Epidemiological Record – DHHS 1030)
   - Recent exposure – exposure within the past two years;
   - Signs and symptoms of TB disease – unexplained productive cough greater than three weeks of duration, anorexia, unexplained weight loss, fever, night sweats or hemoptysis;
   - Previous infection – if individual has taken adequate preventive therapy, TB disease is less likely;
   - Previous disease – if individual has taken inadequate regimen or compliance was poor, TB disease is likely to reoccur;
   - Risk factors – evaluate risk factors for developing disease **(see Chapter II);**
   - HIV infection – individuals with latent TB infection and HIV have a high risk of progression to active TB disease; provide HIV counseling and testing for everyone regardless of age **(see Chapter V for the diagnosis and treatment of TB in HIV positive persons); or**
   - Possible pregnancy – refer for pregnancy testing if indicated.

2. Tuberculin Skin Test (TST) or Interferon Gamma Release Assay (IGRA)
   - Obtain documented TST mm reading **or** administer TST and record mm reading **or** documented IGRA test result **or** obtain IGRA results; IGRA/TST is recommended but not required if the individual is known to be M. tuberculosis culture positive.
   - A positive IGRA/TST may support the diagnosis of TB disease but does not distinguish latent TB infection from active TB disease. A negative IGRA/TST does not exclude the possibility of TB disease.

3. Chest x-ray
   - A posterior-anterior view of the chest is the standard radiograph for adults
   - Children < 5 years of age need a posterior-anterior view and a lateral view chest x-ray.
   - Reactivation TB disease in immunocompetent adults usually occurs in the apical and posterior segments of the upper lobe or in the superior segments of the lower lobe.
   - Individuals suspected of having TB disease **at any site** should have a chest x-ray and sputum smear/culture (if able to provide specimens) to rule out pulmonary involvement.

4. Bacteriology
   - Three sputum specimens should be obtained with an interval of at least eight hours between specimen collections. At least one of these specimens should be an early morning specimen. After the initial three sputum specimens, collect two sputum specimens every two weeks for smear and culture until two consecutive sputum cultures are negative (culture conversion).
   - All initial specimens from any source should have cultures performed.
   - Drug susceptibility testing should be done on all initial isolates.

- Patients who have received prior TB treatment or who come from countries with high rates of drug resistance are recommended to get a specimen (either smear-positive sputum or isolate from a positive culture) sent to the Centers for Disease Control and Prevention for molecular detection of drug resistance. This must be coordinated through the state lab.

5. Diagnostics for suspected TB in children
   - Consultation with a pediatric infectious diseases specialist is indicated when TB in a child is suspected. See chapter IX, section C. for contact information or call your TB Nurse Consultant for assistance in making this contact.
   - If the source case is unknown or the isolate is not available from the source case, obtain specimens from the child via gastric aspirate **(see Chapter IX for procedure)**, BAL, sputum collection or tissue biopsy if extra-pulmonary disease is suspected.
   - If the source case is known, obtain the susceptibility test results to assure effective treatment.
   - If resistance is suspected in the source case or child, obtain specimens from the child for mycobacterial cultures.
   - Consider a lumbar puncture to rule out meningeal tuberculosis for any child <4 years old with TB; a lumbar puncture is <u>strongly recommended</u> in children <2 years of age with suspected TB even in the absence of neurological symptoms.
   - Any child with suspected TB <u>and</u> neurological symptoms should undergo <u>prompt</u> evaluation by a physician, preferably a pediatric infectious disease physician, a lumbar puncture, and an MRI of the brain with contrast.

B. <u>Treatment</u>

1. Standards of TB Disease Management

   a. Patients treated for pulmonary or extra-pulmonary TB should be examined by a physician, physician's assistant or nurse practitioner:
      - Within the first four weeks after presumptive or confirmed TB diagnosis;
      - Any time during treatment if there are signs or symptoms of significant drug toxicity;
      - Any time there is an indication that the patient is not responding to therapy; and
      - During the final month of therapy.

      The exam should focus on signs and symptoms of pulmonary and extra-pulmonary disease at baseline, and resolution of such findings at the end of therapy.

   b. Suspects of any age should have an HIV test. This information is essential to ensure adequate and appropriate treatment.

   c. Isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), plus ethambutol (EMB) is the standard initial four-drug regimen for all HIV-negative non-pregnant individuals.

d. Prior to initiating any TB therapy, review all medications the individual is taking and assess for potential drug interactions. If medications used to treat other conditions are adjusted to account for interactions with TB treatment, it is critical to readjust them to former doses once TB medications are stopped.

e. **Any variation (drugs, dosage, or length of treatment) from the NC recommended regimens is to be discussed with the attending physician and the TB Nurse Consultant or the TB Control Program physician.**

f. All TB drug dosages should be calculated according to mg/kg body weight and rounded up to the next available dose supplied by the manufacturer, not to exceed maximum safe dosage for each drug; **(see dosage table later in this chapter).**

g. Adjust weight-based dosage as weight changes; young children/infants < 4 years old should be weighed monthly.

h. All tuberculosis medications should always be administered at the same time (no split doses and all TB drugs simultaneously).

i. **Directly observed therapy (DOT) is the standard of care for the management of TB disease and is required by law (10A NCAC 41 A .0205 (e)).** Video DOT may be used when appropriate. See more information regarding video DOT in Chapter IX.

j. Never add a single drug to a failing regimen.

k. Every patient must be assessed at least monthly for adverse reactions and the findings documented (DHHS 2810).

l. If response is slow or sub-optimal (failure to convert sputum cultures at the end of 10 - 12 weeks of treatment and/or lack of improvement in initial symptoms), contact your TB Nurse consultant. The individual should be evaluated for adherence, drug absorption, and drug resistance; treatment may need to be prolonged

m. The standard length of treatment for uncomplicated pan-sensitive TB is a minimum of six months (26 weeks) and at least four months of treatment following sputum culture conversion (whichever is longer)

n. **If it is necessary to use second line TB drugs during treatment, the expertise of the TB Control Program physicians should be utilized.**

o. Conversion date is defined as the date of the first sputum specimen collected that does not grow *Mycobacterium tuberculosis*; if subsequent cultures are found to be positive, this negates the conversion.

p. If an individual is unable to produce sputum****** and the attempt to collect a specimen is made under nursing supervision with clear documentation of the effort in the record, this may be considered a “clinical” conversion.

******An attempt to collect an induced sputum by nebulizer should be made if a natural sputum specimen cannot be obtained **(see Chapter IX for procedure).**

q. TB medications in healthcare facilities or institutional/congregate settings should be administered daily by direct observation whenever treating disease.

r. All suspected or confirmed TB cases must be reported to the regional TB Nurse Consultant using the North Carolina Electronic Disease Surveillance System (NCEDSS) within seven days of the patient being identified as a suspect.

s. See variations in the length of treatment under specific regimens found in the remainder of this chapter.

t. The physician should review all lab results and the medical record should indicate that the physician reviewed the lab results.

2. Standard Regimen for HIV-negative Adults ≥ 15 yr. with Pulmonary TB

a. The **intensive phase** (8 weeks) is intended to rapidly reduce the number of tubercle bacilli in the body. This phase consists of four-drug therapy:

- INH, RIF, PZA, EMB, daily DOT for 8 weeks (56 doses, 40 of which must be directly observed);
  - If local program resources make daily therapy logistically unfeasible during the first two months, an alternative is to treat with daily DOT for 2 weeks (14 doses, of which 10 must be directly observed), followed by thrice-weekly DOT (**dose must be increased for intermittent therapy)** for 6 weeks (18 thrice-weekly doses).
  - Patients with HIV infection, positive sputum smears, and/or cavitary disease should be given highest priority for daily therapy during the intensive phase
- **If PZA is not included in the initial regimen, the first eight weeks of treatment must be administered by daily DOT;**
- If PZA is not included in the regimen within the first 2 weeks of treatment or PZA is contraindicated, a minimum of **nine months** of INH and RIF is required**.** (two months of PZA at the beginning of treatment is required for a six month or short course regimen to be effective);
- Discontinue PZA after eight weeks if the organism is fully susceptible to INH and RIF and the patient is tolerating both drugs or after eight weeks if the initial cultures were negative and the individual is clinically improving; and
- Discontinue EMB when either a) drug susceptibility testing on the initial positive culture indicates that the organism is fully susceptible to INH and RIF and these drugs will remain in the regimen or b) at eight weeks when an individual with negative cultures is determined to be improving clinically and tolerating the remaining drugs.

b. The **continuation phase** (18 weeks) is intended to eliminate the smaller number of organisms that persist. If treatment is not continued long enough, some bacilli may survive and cause TB disease later.
   - For most patients, this should consist of isoniazid and rifampin thrice weekly DOT for 18 weeks (54 thrice-weekly doses). A week may be counted if at least two DOT doses are ingested during that week.
   - Patients with HIV infection, positive acid-fast smears, and/or cavitary disease on plain chest radiographs are recommended to receive daily therapy for 18 weeks (with DOT given 5 days in 7, equal to 90 daily DOT doses) if local program resources permit.
   - Twice-weekly DOT for 18 weeks (36 twice-weekly doses) is acceptable for smear-negative, HIV-negative patients without cavities on plain chest radiographs. A week may be counted only if two DOT doses are ingested during that week.

c. For patients who are initially sputum culture positive, sputum specimens must be collected every two weeks after treatment is initiated until a series of two cultures have converted to negative.

d. If the patient has a cavity on initial x-ray **and** fails to convert two sputum specimens to negative within the first two months of treatment (based on the collection date), treatment must be extended for a total of nine months **(continuation phase of 31 weeks).**

3. Regimen for HIV-negative Pregnant Women

a. INH, RIF, and EMB daily for eight weeks DOT (initial phase) followed by 31 weeks of INH and RIF (if fully susceptible) thrice weekly DOT (continuation phase). (56 daily doses (40 must be by DOT) plus 93 thrice-weekly doses):
   - The first eight weeks of medicine must be administered on a daily basis since PZA is not routinely used during pregnancy; and
   - Discontinue EMB when initial culture results confirm it to be susceptible to INH and RIF – or at eight weeks if the initial cultures were negative **and** the individual is clinically improving.
   - Any week in which at least two DOT doses are received may be counted toward the total length of treatment

b. **PZA** is not routinely used in the United States in HIV-negative pregnant women because its effect on the fetus is unknown. However, for severe cases of TB or on advice of a NC TB Medical Consultant, PZA may be used in pregnancy.

c. **Streptomycin** should not be used when treating pregnant women because it interferes with the development of the ear and may cause congenital deafness.

d. Vitamin B6 should be given due to the risk for peripheral neuropathy in pregnancy.

e. INH, RIF and EMB all cross the placenta, but these drugs have not been demonstrated to have teratogenic effects on the fetus.

f. Small concentrations of TB medications in breast milk do not produce toxicity in the nursing newborn; therefore, breast-feeding should not be discouraged. **(see Chap. III regarding breast-feeding and B_6).**

4. Regimen for HIV-negative Infants and Children (<15 yr.)

a. Refer to special diagnostics on page one of this chapter when TB in a child is suspected and obtain consultation from a pediatric infectious disease specialist.

b. Treatment of suspected central nervous system (CNS) TB should include corticosteroids in addition to the standard TB drugs.

c. **Initial phase** (8 weeks) is intended to rapidly reduce the number of tubercle bacilli in the body. This phase consists of:

- INH, RIF, PZA, and EMB, daily DOT for eight weeks (56 doses, 40 of which must be directly observed.
- In the setting of limited disease (i.e. smear-negative, non-cavitary pulmonary disease), daily DOT for two weeks (14 doses, 10 of which must be directly observed) followed by thrice-weekly DOT for six weeks (doses must be increased as noted in the table) is acceptable. Twice-weekly DOT is acceptable after the first two weeks if approved by the state pediatric TB consultant or state TB medical director.
- Use EMB with caution for children who are unable to be vision-tested; and
- INH dosing for children can be calculated as follows:

Tablets:	To calculate number of kg, divide individual's weight by 2.2. (1 kg = 2.2 lbs.). Multiply weight in kg by recommended mg per kg based on daily or twice weekly regimen.
INH syrup:	To calculate number of kg, divide individual's weight by 2.2. (1 kg = 2.2 lbs.). Multiply weight in kg by recommended mg per kg based on daily or twice weekly regimen. INH syrup concentration is 10 mg/cc.

d. **Continuation phase** (18 weeks) is intended to eliminate the smaller number of organisms that persist. If treatment is not continued long enough, some bacilli may survive and cause TB disease later. This phase consists of INH and RIF twice weekly DOT for 18 weeks (36 twice-weekly doses):

- Discontinue EMB when initial cultures results confirm the TB organism is susceptible to INH and RIF or at eight weeks if the initial culture results were negative **and** the child is clinically improving; and
- Discontinue PZA after eight weeks if the organism is fully susceptible to INH and RIF and the patient is tolerating both drugs or after eight weeks if the initial cultures were negative and the individual is clinically improving.

- Children and adolescents with extensive or cavitary disease should receive daily DOT for 18 weeks as described for adults above (line item 2b).

e. Infants and children with meningeal, bone/joint or miliary TB should receive a minimum of 9-12 months of treatment.

f. If PZA is not included in the first eight weeks, the initial phase of treatment must be administered by daily DOT and the regimen must be extended to nine months.

g. Infants and children should be weighed monthly and drug dosages adjusted accordingly.

h. Children weighing more than 40 kg should be dosed as adults.

i. Chest x-rays of children with hilar adenopathy may not become normal for two-to-three years after treatment. A normal chest x-ray is not required to consider treatment complete.

5. Regimen for HIV-negative Non-Pregnant Adults with Smear and Culture Negative Pulmonary TB

a. Treatment consists of INH, RIF, PZA, and EMB for eight weeks. (56 daily doses,40 of which must be directly observed) At the completion of eight weeks of treatment, discontinue PZA and EMB and continue with INH and RIF thrice-weekly for a total of 16 weeks of treatment (24 additional thrice-weekly doses) (**if HIV-positive, treat for a total of 26 weeks; see Chapter V for further information).**

b. Obtain a chest film after two months of treatment. If there is no improvement on x-ray, consult the physician regarding a possible change in the diagnosis.

c. If the source case is known to have drug resistant TB, refer to the regimens for resistant TB in this chapter.

6. Regimen for HIV-negative Adults with Extra-pulmonary Tuberculosis

Individuals with TB disease at any site should have a chest x-ray and sputum specimens for smear/culture (if able to produce sputum) done during the diagnostic phase to rule out pulmonary involvement.

a. Extra-pulmonary TB can be treated with the same drug regimens and for the same length of time as pulmonary TB (standard six-month regimen - 26 wks) with the following exceptions:

- Meningeal/CNS TB should be treated for 9-12 months based on response to treatment;
- Bone/joint TB should be treated for 6-9 months based on response to treatment; and

- If there are questions regarding a prescribed treatment regimen, please consult with the N.C. TB Control Program.

b. Corticosteroids can be beneficial in improving survival in patients with TB meningitis, particularly if administered early in the course of disease. They should be administered in most cases of TB meningitis according to the current ATS/CDC/IDSA guidelines:
   - TB meningitis: The recommended regimen is dexamethasone in an initial dose of 8 mg/day for children weighing less than 25 kg and 12 mg/day for children weighing 25 kg or more. This dose should be continued for one week, with a gradual tapering down each week for the next 5 weeks, with discontinuation after 6 weeks. Adults with severe disease (grade II or III, corresponding to Glasgow Coma Scale scores below 15 or with focal neurologic signs) should receive the following dexamethasone regimen:
     - 0.4 mg/kg daily for 1 week, followed by
     - 0.3 mg/kg daily for 1 week, followed by
     - 0.2 mg/kg daily for 1 week, followed by
     - 0.1 mg/kg daily for 1 week, followed by
     - 4 mg daily for 1 week, followed by
     - 3 mg daily for 1 week, followed by
     - 2 mg daily for 1 week, followed by
     - 1 mg daily for 1 week, then stop
   - Adults with less severe disease (grade I, corresponding to Glasgow Coma Scale score of 15 and no focal neurologic signs) should receive the following dexamethasone regimen:
     - 0.3 mg/kg daily for 1 week, followed by
     - 0.2 mg/kg daily for 1 week, followed by
     - 0.1 mg/kg daily for 1 week, followed by
     - 3 mg daily for 1 week, followed by
     - 2 mg daily for 1 week, followed by
     - 1 mg daily for 1 week, then stop

7. Rifapentine (RPT) Option for Treating HIV-negative Adults ≥ 18 years old

   a. Once weekly INH and RPT is no longer recommended for general use in treating active TB.

8. Treatment of M. bovis Including BCG Strain

   a. If M. bovis is isolated from urine specimens following intravesical BCG treatment, treatment for TB disease will depend on the extent of clinical manifestations of TB disease.

   b. If M. bovis is isolated from pulmonary specimens following intravesical BCG treatment, the patient should receive treatment for tuberculosis disease.

   c. If you receive a positive M. tuberculosis complex culture report on an individual who has been treated with BCG for bladder cancer, notify your nurse consultant.

d. M. bovis is always resistant to PZA.

e. Use INH and RIF for the initial regimen and treat for nine months (39 weeks) using daily administration during the first eight weeks.

Remember that M. bovis is one of the organisms found in the *Mycobacterium tuberculosis* complex **(see Chapter IX, Laboratory Services)**. If drug susceptibility testing shows mono-resistance to PZA, the disease is likely due to M. bovis and the state lab will run further studies to determine if it is the BCG strain.

C. Drug Resistant TB

1. Patients who are resistant to TB drugs will need an alternative regimen. The alternative regimen should be discussed with a state TB Medical Consultant on a case-by-case basis.

2. Primary resistance occurs when resistant tubercle bacilli are isolated before any TB drugs are administered. Patients with risk factors for primary resistance should have an early specimen (smear-positive sputum or positive culture) sent for molecular detection of drug resistance (MDDR testing). Risk factors for primary resistance are:

   a. Exposure to a TB patient who has drug-resistant TB disease;
   b. Being from a country with a high prevalence of drug resistance; and
   c. Residing in a population with $\geq$ 4 percent resistance to INH

3. Acquired resistance occurs when resistant tubercle bacilli are isolated during treatment or isolated from those who have been treated in the past. Risk factors for acquired resistance are:

   a. Individuals who do not follow their prescribed treatment schedule;
   b. Inadequate or inappropriate drug regimen; and
   c. Malabsorption (can lead to sub-therapeutic serum drug levels).

4. Regimens for INH Resistance or Intolerance **(Consult with a State TB Medical Consultant)**

   a. Individuals on an initial regimen of INH, RIF, PZA, and EMB:
      - Discontinue INH; continue to treat with RIF, PZA, and EMB for a total of six months (26 weeks). A fluoroquinolone may be added to this regimen, particularly in cases of extensive disease.

   b. Individuals on an initial regimen of INH, RIF, and EMB (no PZA):
      - Discontinue INH; continue to treat with RIF and EMB;
      - A fluoroquinolone may be added to this regimen, particularly in cases of extensive disease
      - The initial phase (the first eight weeks) must be administered by daily DOT); and
      - Treat for a minimum of 12 months.

   c. Individuals on initial regimen of INH and RIF:

- Repeat susceptibility studies;
- Discontinue INH and continue RIF; and
- Add PZA and EMB to the regimen if susceptible to these two drugs and then treat for six months (26 weeks) with the three drugs. A fluoroquinolone may be added to this regimen, particularly in cases of extensive disease.

5. Regimen for RIF Resistance or Intolerance **(Consult with a State TB Medical Consultant)**

   a. Individuals on initial regimen of INH, RIF, PZA, and EMB:
      - Discontinue RIF;
      - Continue to treat with INH, PZA and EMB daily during the initial phase (the first eight weeks);
      - Strongly consider adding a fluoroquinolone to this regimen and
      - After the initial phase continue INH and EMB (+/- fluoroquinolone) daily or intermittently
      - Treat for a total of 18 months (78 weeks).

6. Regimen for PZA Resistance or Intolerance **(Consult with a State TB Medical Consultant)**

   a. An "M. tuberculosis complex" isolate that is PZA monoresistant is likely to be M.bovis which is always PZA resistant. M.bovis can be acquired through unpasteurized milk or cheese, and, if the site of disease is pulmonary, can be spread to others.

   b. Individuals on an initial regimen of INH, RIF, PZA and EMB:
      - Discontinue PZA and EMB if sensitive to RIF and INH;
      - Treat with INH and RIF for nine months (39 weeks); and
      - The initial phase (the first eight weeks) must be administered by daily DOT.

7. Multi-Drug Resistant TB (MDR-TB) **(Consult with a State TB Medical Consultant)**

   a. MDR-TB is resistant to both INH and RIF and may also be resistant to other first or second line drugs.

   b. Treatment must be individualized and prolonged based on medication history and susceptibility studies.

   c. Give at least three medications to which the organism is susceptible.

   d. The regimen should continue until sputum conversion is documented, followed by at least 12 months of treatment.

   e. Only daily therapy is used in the treatment of MDR-TB.

   f. **The N.C. TB Control Program should be consulted regarding the treatment regimen whenever treating an MDR-TB case.**

D. Pyridoxine (B_6)

1. Peripheral neuropathy is associated with INH but is uncommon at dosages of 5 mg/kg of body weight.

2. Patients with the following conditions in which neuropathy is common should receive B_6 25 mg. daily or 50 mg twice or thrice weekly:
   - Diabetes mellitus;
   - Average alcohol use of >three drinks per day;
   - Malnutrition;
   - HIV infection;
   - Pregnancy; and
   - Seizure disorder.

3. Pyridoxine (B_6) is recommended for exclusively breastfed infants and for children and adolescents on milk and meat and deficient diets; children with nutritional deficiencies, including all symptomatic HIV-infected children:

   - Dosage for infants and children (contact physician for order): 1 mg/kg body weight (maximum 25mg daily).

4. Individuals that develop peripheral neuropathy while taking daily B6 should have their B_6 dose doubled. If neuropathy is not resolved within two weeks, consult the physician.

5. Individuals on dialysis should be given B_6 50mg on the same schedule as INH

E. Dosing for Adults with Reduced Renal Function (creatinine clearance <30ml/min) on Hemodialysis [1]

1. Medications should be given after hemodialysis on the day of dialysis (dialysis is normally done three-times-a-week).

   a. Monitoring of serum drug concentrations should be considered to ensure adequate absorption and to assist in avoiding toxicity.

   b. Ethambutol is difficult to manage in renal insufficiency and therefore is used less often, usually only when resistance is an issue.

   c. There is no clinical evidence for using 250 mg of cycloserine daily; there should be careful monitoring for evidence of neurotoxicity.

Isoniazid	No change	300 mg daily or 900 mg twice or thrice weekly
Rifampin	No change	600 mg daily or twice or thrice weekly
Pyrazinamide		25-35 mg/kg thrice weekly (not daily)
Ethambutol		20-25 mg/kg thrice weekly (not daily)
Levofloxacin		750-1000 mg thrice weekly (not daily)
Moxifloxacin	No change	400 mg daily

Cycloserine		250 mg daily or 500 mg thrice weekly
Ethionamide	No change	250-500 mg daily
PAS	No change	4 grams, twice daily
Streptomycin		15 mg/kg twice or thrice weekly (not daily)
Capreomycin		15 mg/kg twice or thrice weekly (not daily)
Kanamycin		15 mg/kg twice or thrice weekly (not daily)
Amikacin		15 mg/kg twice or thrice weekly (not daily)

[1] Nahid P et al, Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Disease Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. Clinical Infectious Diseases 2016; 63(7): e147-195.

F. Directly Observed Therapy

1. **Directly Observed Therapy (DOT) is the standard of care for the management of TB disease and is required by law (10A NCAC 41 A .0205 (e)).**

2. Directly Observed Therapy (DOT) is the documented actual observation of medication ingestion by a health care worker (HCW)**.** This specifically excludes family members and significant others. Video DOT may be used when appropriate. See chapter IX for guidance about video DOT.

3. Document each DOT dose on the back of the Tuberculosis Drug Record (DHHS 1391).

   a. When DOT is delegated to a health care worker outside the health department, the TB nurse retains ultimate responsibility for documenting the monthly patient assessment (regardless of who observed the medication ingestion) and for patient management.

   b. Document the observer's understanding and willingness to:
      - Assume responsibility for actual observation of ingestion;
      - Document ingestion of TB drugs;
      - Report to PHN any patient complaints;
      - Notify PHN immediately when dose(s) are missed; and
      - Request relief from DOT responsibility if does not wish to continue.

4. Daily DOT must be administered Monday through Friday. Unit doses may be self-administered on weekends; five DOT doses are considered a DOT week.

5. Thrice weekly DOT requires a physician's order to increase the dosage and is administered on a Monday/Wednesday/Friday schedule.

6. Twice weekly DOT requires a physician's order to increase the dosage and is administered on a Monday/Thursday or Tuesday/Friday schedule.

7. Twice and thrice weekly dosages should not be given to the patient to self-administer. If the patient must self-administer, such as, during a vacation, daily dosing should be given to the patient to self-administer.

8. Twice weekly DOT scheduling should be adjusted for holidays so that both doses can be given by DOT that week; it is permissible to give both twice weekly doses at least 48 hours apart if holidays require doing so.

9. In order to ensure that all doses are administered by DOT, please make up any self-administered doses (except weekends) with a DOT dose; this will allow for 100 percent DOT when reporting to the TB Control Program using the CDC Follow Up 2 form and will ensure adequate treatment.

G. Monitoring

1. Baseline Evaluation

a. The TB Nurse needs to visit the patient either in the hospital or in the home as soon as possible after notification to establish a working relationship.

b. Obtain medical history using the TB Epidemiological (EPI) Record (DHHS 1030).

c. Complete a baseline evaluation using the Tuberculosis Flow Sheet (DHHS 2810).

d. Obtain a signed TB Treatment Agreement **(see sample agreement later in this chapter)**. Include the following in the document:
- Treatment regimen and frequency;
- Required monitoring e.g. x-rays, sputum, lab work, appointments; and
- Other requirements pertinent to the situation.

e. If infectious, advise the patient to remain at home, exclude outside visitors and wear a mask to medical appointments until s/he becomes non-infectious as determined by the health department.

f. Collect supervised sputum regardless of prior pulmonary or pleural specimens obtained elsewhere. Provide individual with two additional containers for collection of consecutive early morning specimens to be sent to the State Laboratory. **(refer to Chapter IX for procedure).**

g. Have patient identify persons at risk for exposure and possible infection and prepare a list of contacts for tuberculin skin testing or IGRA testing.

h. Obtain documented TST mm reading **or** administer TST and record mm reading **or** documented IGRA test result **or** obtain IGRA and record results; IGRA/TST is recommended but not required if the individual is known to be M. tuberculosis culture positive.

i. Draw blood or obtain laboratory results for those ≥15 years old including:
- Hepatic function panel;
- Serum creatinine; and

- CBC with platelet.

j. Consult physician if any baseline laboratory test is abnormal; if within normal limits, no further testing is necessary unless the patient has evidence of toxicity.

k. All children and adults should have HIV testing done or results documented.

l. Individuals taking Ethionamide or p-Aminosalicylic acid (PAS) should have baseline thyroid function tests (e.g.,TSH).

m. Individuals taking Streptomycin, Amikacin, Kanamycin, or Capreomycin should have BUN and Creatinine monitored at baseline.

n. Individuals taking Capreomycin should have potassium and magnesium monitored at baseline.

o. Baseline visual acuity (Snellen) and color perception testing (red/green-Ishihara test) on individuals to be treated with ethambutol.

p. Perform baseline hearing/ataxia testing on individuals to be treated with streptomycin (SM), Capreomycin, Kanamycin, and Amikacin using screening audiometry and tandem gait test (heel-to-toe in a straight line for four-six steps).

q. Calculate and verify each prescribed medication dosage. Calculate on the lower figure in the range and round up to the next available dose supplied by the manufacturer; any dosage within the therapeutic range is acceptable.

r. If the specimen submitted is NAAT positive (i.e. PCR positive) or culture positive for M.tb and the patient is at high risk for rifampin or MDR resistance (previously treated for TB, a contact to a drug resistant case or is from a country with a high incidence of drug resistant TB) have the state lab submit an isolate to the CDC for Molecular Detection Drug Resistance (MDDR) testing.

2. Follow-up monitoring

a. Complete the Tuberculosis Flow Sheet (DHHS 2810) monthly.

b. Make a home visit to:
- Further identify personal and socioeconomic barriers to treatment adherence; and
- Re-interview to ensure all contacts have been identified.

c. Obtain a set of two consecutive early morning sputum specimens every two weeks (if diagnostic specimen was sputum), until cultures convert to negative. **Supervise the collection of one specimen in each set.**

d. Check visual acuity (Snellen) and color perception (red/green, Ishihara test) **monthly** while individual is taking EMB. Report any changes in visual acuity or color perception to the TB physician.

e. Individuals taking ethionamide or p-aminosalicylic acid (PAS) should have thyroid function monitored monthly

f. Individuals taking Streptomycin, Amikacin, Kanamycin, or Capreomycin should have BUN and Creatinine monitored at least weekly.

g. Individuals taking Capreomycin should have potassium and magnesium monitored monthly.

h. Perform hearing acuity using screening audiometry and tandem gait test (heel-to-toe in a straight line for four-six steps) monthly while individual is taking SM, capreomycin or amikacin, or kanamycin. Report any changes in audiometric screening or tandem gait testing to the TB physician.

i. Obtain monthly hepatic function panel for the following individuals:
- Abnormal baseline hepatic function;
- Pregnant or up to 3 months postpartum;
- Those with symptoms of adverse reactions;
- Persons taking potentially hepatotoxic drugs;
- Persons with chronic active hepatitis B or those with hepatitis C;
- Chronic or binge use of alcohol; and
- Those with HIV infection.

j. Consult physician anytime hepatic function testing results are abnormal.

k. If the patient does not clinically improve and/or sputum cultures do not convert from positive to negative within 10-12 weeks:
- Arrange for patient to be evaluated by a physician or mid-level provider;
- Repeat susceptibilities testing on latest positive MTB sputum culture if cultures are still positive at 10-12 weeks;
- Consult with regional TB nurse consultant regarding serum drug levels. Information regarding serum drug levels may also be found in chapter IX; and
- Consult with the state TB medical clinician to discuss serum drug level results, appropriate dosing of TB medicines, and length of therapy.

l. Review at least monthly for hepatotoxicity and other drug reactions:
- Nausea;
- Vomiting;
- Loss of appetite;
- Dark urine (cola color);
- Yellow skin or sclera;
- Malaise;
- Abdominal tenderness;
- Unexplained fever of three-or-more days;

- Unexplained abdominal bloating;
- Rash;
- Pruritus;
- Paresthesias of the hands or feet;
- Bruising;
- Flu-like symptoms; and
- Abnormal bleeding.

m. If the individual exhibits signs or symptoms of possible toxicity:
- Temporarily stop the medications.
- Do lab work appropriate to symptoms.
- Contact the prescribing physician to discuss symptoms, lab results, and any needed changes in the treatment plan.
- Patients with confirmed or strongly suspected TB should not remain off all TB medications for much longer than a week. Consultation with one of the State TB physicians should be initiated if there is any question or delay in finding an acceptable treatment regimen

n. Obtain a chest x-ray after two months of treatment if pre-treatment culture results were negative. If no improvement on x-ray, consult physician regarding possible change in original diagnosis.

o. Obtain a chest x-ray during the final two weeks of therapy on all individuals with pulmonary and pleural TB disease. This provides a comparison film for future reference. **Length of treatment should not be based on end of treatment chest x-ray results**.

p. The patient should be evaluated by the referring physician, primary care provider or health department TB physician in the final weeks of treatment.

q. Discharge the individual from service after providing education and instructions to return if symptoms occur. A record of completion of TB treatment should be given to the patient to keep as part of his personal medical record.

H. TB Drug Adverse Reactions

Evaluation of all adverse reactions should include a hepatic function panel to rule out hepatotoxicity and consultation with the prescribing physician.

1. Rash

a. If the rash is minor and or manifested primarily by itching, the medical provider may treat with antihistamines which may provide symptomatic relief.

b. If the rash is petechial, it may be due to rifampin induced thrombocytopenia. Stop TB medicines and contact TB physician. Obtain order for CBC with diff and platelets and a hepatic function panel and report results to TB physician as soon as possible. If rifampin is discontinued due to thrombocytopenia notify regional nurse consultant.

c. If there is a generalized erythematous rash, particularly if associated with fever and/or mucous membrane involvement, stop all drugs immediately and notify physician.

d. If patient experiences swelling of the face, throat or difficulty breathing, call 911 and activate emergency services immediately.

2 Nausea/vomiting and other GI distress

a. Obtain a hepatic function panel to rule out hepatotoxicity.

b. If no hepatotoxicity is present, the provider should consider the use of an anti-nausea medicine 30 minutes before the TB medications are administered or offer TB drugs with food.

3. Hepatotoxicity

a. If signs and symptoms of hepatotoxicity are **present**:
- Temporarily stop medications;
- Draw hepatic function panel;
- Contact the prescribing physician to discuss symptoms and lab results and any needed changes in the treatment plan;
- The prescribing physician should refer to the hepatotoxicity flowchart at the end of chapter III; and
- Contact the regional TB Nurse Consultant if ALT>3 times the upper limit of normal (ULN) or the bilirubin is > 2.5.

b. If signs and symptoms of hepatotoxicity are **not present**, manage individuals according to hepatotoxicity flowchart at the end of chapter III.

c. Hepatitis due to other causes needs to be ruled out using appropriate serologies e.g., HBsAg, antiHBc-lgM, HAV IgM, HCV.

d. Changes to a standard four drug TB regimen (INH, RIF, EMB, PZA) must be okayed by a state TB medical consultant.

I. <u>Reintroduction of TB Medication for Hepatotoxicity</u>

1. **Stop all TB medications if lab work is abnormal and consult physician.** Patients with confirmed or strongly suspected TB should not remain off all TB medications for much longer than a week. Consultation with one of the State TB physicians should be initiated if there is any question or delay in finding an acceptable treatment regimen.

2. Monitor liver enzymes until level reflects a continuing decrease before restarting any TB drugs (< 2x ULN).

3. Reintroduce drugs in the following order (see protocol below):
- ethambutol (EMB) and rifampin (RIF).
- isoniazid (INH).

- pyrazinamide (PZA).
- PZA is reintroduced only if individual has not completed the initial eight weeks of PZA. Incremental dosing of PZA as follow: 500 mg on day 11; 1000 mg on day 12; 1500 mg on day 13; and full dose daily thereafter.
- EMB is reintroduced at a full therapeutic dose if drug susceptibilities are not yet available and the drug is needed for the initial treatment regimen.

4. Monitor liver enzyme levels weekly and evaluate results before adding another drug to the regimen.

5. Because reintroduction takes approximately three weeks, it may be prudent to give at least 3 non-hepatotoxic TB drugs during this time, e.g., EMB, SM and a quinolone.

6. Contact North Carolina Tuberculosis Control for assistance in determining the appropriate length of therapy once reintroduction of drugs is complete and therapeutic dosages are achieved.

J. Suggested Flow Chart for Reintroducing TB Medications (daily administration)

Week #1:

Dose #1	EMB (full dose), RIF 600 mg
Dose #2	EMB, RIF 600 mg
Dose #3	EMB, RIF 600 mg.
Dose #4	EMB, RIF 600 mg
Dose #5	EMB, RIF 600 mg

Draw hepatic function panel

Week #2:

Dose #6	EMB, RIF 600 mg, INH 300 mg
Dose #7	EMB, RIF 600 mg, INH 300 mg
Dose #8	EMB, RIF 600 mg, INH 300 mg
Dose #9	EMB, RIF 600 mg, INH 300 mg
Dose #10	EMB, RIF 600 mg, INH 300 mg

Draw hepatic function panel

Week #3:

Dose #11	EMB, RIF 600 mg, INH 300 mg, PZA 500 mg
Dose #12	EMB, RIF 600 mg, INH 300 m, PZA 1000mg
Dose #13	EMB, RIF 600 mg, INH 300mg, PZA 1500 mg
Dose #14	EMB, RIF 600 mg, INH 300mg, PZA full dose
Dose #15	EMB, RIF 600 mg, INH 300mg, PZA full dose

Draw hepatic function panel

K. Airborne Precautions and/or Home Isolation

1. Transmission of TB is dependent upon four factors:
   a. Number and/or viability of bacilli expelled in air (index case characteristics);
   b. Susceptible host (contacts);

c. Environment (shared air); and
d. Duration and/or frequency of exposure (time).

2. Individuals newly suspected of having pulmonary or laryngeal TB are considered infectious and should be managed using airborne precautions with no new persons exposed until the following conditions have been met:
   a. Individuals who are initially sputum smear positive should be maintained in negative pressure isolation while in the hospital or restricted to their home until:
      - Two sputum specimens (induced or natural) are collected, with a minimum interval of eight hours between specimens are found to be smear negative for AFB;
      - They have been compliant on TB medicine to which the organism is judged to be susceptible: and
      - They show evidence of clinical improvement.
   b. Individuals initially sputum smear negative should be maintained in negative pressure isolation while in the hospital until they have been compliant on tuberculosis medications to which the organism is judged to be susceptible and there is evidence of clinical improvement on treatment.
   c. Individuals needing respiratory precautions may be discharged to their home regardless of sputum smear status with instructions to remain in the home, avoid exposing anyone other than already exposed household members and to avoid contact with infants and young children and immuno-compromised individuals. The local health department will advise when the precautions can be lifted based on length of treatment and sputum smear status.
   d. It is critical that a person with positive smears not be permitted to return to an institutional or congregate setting, a setting with infants and children, or a setting where immunocompromised individuals are located. An outdoor work environment may be permissible in some circumstances; this first needs to be discussed with the nurse consultant.
   e. Persons with suspected or known active pulmonary or laryngeal TB who are initially sputum smear negative and who will be managed at home (not in the hospital) do not require respiratory isolation once they have been started on tuberculosis treatment.

3. Hospitalized pediatric TB suspects and cases should be managed in accordance with specific pediatric infection control policies. Parents or guardians should be evaluated for TB disease early in the hospital stay.

   "Children younger than 10 years of age with primary tuberculosis rarely are contagious because their pulmonary lesions are small (paucibacillary disease), cough is not productive, and few or no bacilli are expulsed." (American Academy of Pediatrics. *Tuberculosis*. In: Pickering LK, ed. Red Book: 2006 Report of the Committee on Infectious Diseases, 27th ed. Elk Grove Village, IL: American Academy of Pediatrics, 2006: 680.

L. Reporting Cases

1. Report cases to the TB Control Program that meet the laboratory or clinical TB case definition.

a. Laboratory confirmed cases
   - Isolation of M. tuberculosis complex from a clinical specimen. The use of rapid identification techniques for M. tuberculosis performed on a culture from a clinical specimen, such as DNA probes and high-pressure liquid chromatography (HPLC), is acceptable under this criterion.
   - Demonstration of M. tuberculosis from a clinical specimen by nucleic acid amplification (NAA) test. NAA tests must be accompanied by cultures of mycobacterial species. However, for surveillance purposes, CDC will accept results obtained from NAA tests approved by the FDA and used according to the approved product labeling on the package insert, or a test produced and validated in accordance with applicable FDA and Clinical Laboratory Improvement Amendments (CLIA) regulations.
   - Demonstration of acid-fast bacilli (AFB) in a clinical specimen when a culture has not been or cannot be obtained or is falsely negative or contaminated; historically this criterion has been most commonly used to diagnose TB in the postmortem setting.

b. Clinical case definition– In the absence of laboratory confirmation of M. tuberculosis complex after a diagnostic process has been completed, persons must have **all** of the following criteria for clinical TB:
   - Evidence of TB infection based on a positive tuberculin skin test result or positive interferon gamma release assay for M. tuberculosis.
   - One of the following:
     - Signs and symptoms compatible with current TB disease, such as an abnormal chest radiograph or abnormal chest computerized tomography scan or other chest imaging study; or
     - Clinical evidence of current disease (e.g., fever, night sweats, cough, weight loss, hemoptysis.
     - Current treatment with two or more anti-TB medications.

c. A final diagnosis should be made by the TB clinician, in conjunction with the treating physician if indicated, within two months of initiating therapy.

d. Submit the Report of Verified Case of TB (RVCT) and Follow Up 1 report in NCEDSS to the TB Nurse Consultant for your county when drug susceptibilities are known and within three months of initiating treatment.

2 Special Reporting Situations

a. Immigrants, refugees, permanent resident aliens, border crossers, and foreign visitors
   - Immigrants and refugees who are examined after arriving in the United States and diagnosed with clinically active TB requiring anti-TB medications should be counted by the locality of their current residence at the time of diagnosis regardless of citizenship status.

- Border crossers and permanent resident aliens who are diagnosed with TB and plan to receive anti-TB therapy from a locality in the United States for 90 days or more should be counted by the locality of current residence.

b. Out-of-state or out-of area residents
   - A person's TB case should be counted by the locality in which he or she resides at the time of diagnosis. TB in a person who has no address should be counted by the locality that diagnosed and is treating the TB. The TB control officer should notify the appropriate out-of-state or out-of-area TB control officer of the person's home locality to (1) determine whether the case has already been counted to avoid "double counting;" and (2) agree on which TB control office should count the case if it has not yet been counted.

c. Migrants and other transients
   - Persons without any fixed U.S. residence are considered to be the public health responsibility of their present locality and their TB case should be reported and counted where diagnosed.

d. Federal facilities (e.g., military and veterans administration facilities)
   - Cases in military personnel, or dependents, or veterans should be reported and counted by the locality where the persons are residing in the United States at the time of diagnosis and initiation of treatment. However, if military personnel or dependents are discovered to have TB at a military base outside the United States but are referred elsewhere for treatment (e.g., a military base located within the United States), the TB case should be reported and counted where treated and not where the diagnosis was made.

e. Indian health services
   - TB should be reported to the local health authority (e.g., state or county) and counted where diagnosed and treatment initiated. However, for a specific group such as the Navajo Nation, which is geographically located in multiple states, health departments should discuss each case and determine which locality should count the case.

f. Correctional facilities (e.g., local, state, federal, and military)
   - Persons who reside in local, state, federal, or military correctional facilities may frequently be transferred or relocated within and/or between various correctional facilities. TB in those persons should be reported to the local health authority and counted by the locality where the diagnosis was made and treatment plans were initiated.

g. Peace Corps, missionaries, and other citizens residing outside the United States
   - TB in persons diagnosed outside the United States should not be counted. TB in these persons should be counted by the country in which they are residing regardless of their plans to return to the United States for further work-up or treatment.

h. If TB recurs (relapse) in an individual **and** if more than 12 months have elapsed since the individual completed treatment, the recurrence is considered a separate episode and should be counted as a new case.

i. If the case is lost to follow-up but is then located and restarted on treatment, this is not a separate episode; the RVCT Follow Up 2 form should be updated to reflect a new Reason Therapy Stopped and Date Stopped when the person completes treatment or has another outcome.

j. Notify the state of residence or state to which a NC case is moving using the Interjurisdictional TB Notification Form **(see Chapter X for instructions and form)**; a copy of the form should be placed in the patient's record.

k. Forward information regarding cases with residence in another North Carolina county to the appropriate county for case counting.

l. Obtain assistance from the N.C. TB Control when making international referrals.

M. HIV Reporting

TB in persons who are HIV-positive is an AIDS defining condition.

Verify that a CD card and Adult HIV/AIDS Confidential Case Report (CDC 50-42A) have been sent to the HIV/STD Section for TB cases who are HIV-positive.

N. Death Certificates

1. Review and investigate death certificates that list TB as a cause of death or contributing condition. Count as a TB case if confirmed and not previously reported.

2. If TB was not the cause of death, ask the physician to amend the death certificate as follows:

   a. Attending physician completes Supplemental Report of Cause of Death **(DHHS 2263);**

   b. Original DHHS 2263 is forwarded to Vital Records in Raleigh;

   c. One copy is kept at health department; and

   d. One copy is sent to Register of Deeds in the county where the individual died.

O. Patient Non-Adherence

1. Evaluate for barriers to adherence at initial patient contact. The following factors should be taken into consideration:

- Lack of social or family support;
- Alcohol abuse;
- Substance abuse;
- Homelessness;
- History of non-adherence in other health care situations; and
- Mental and/or emotional instability.

2. Evaluate for non-adherence during the treatment phase, such as:
   - Refusing medication;
   - Taking medication inconsistently;
   - Failing to keep DOT appointments; and
   - Missing clinic appointments.

3. If the patient does not abide by the TB Treatment Agreement (see sample agreement in this chapter) **or** has missed a total of two weeks treatment during the initial phase or three weeks of treatment during the continuation phase, then an Isolation Order should be issued by the Health Director.

4. The intent of the Isolation Order is to ensure that the patient has been fully informed of the legal requirements for treating disease and understands legal action can be taken if there is any non-adherence from that date forward. Do not issue an Isolation Order and then fail to follow up with legal action if it becomes necessary.

5. An Isolation Order does not have to be issued before taking out a warrant for the arrest of a health law violator.

6. If there is reason to believe that the patient may board an airplane while infectious, contact N.C. TB Control with assistance is having the patient's name added to the Do Not Board list.

P. N.C. Public Health Laws and TB

See Chapter XI for complete language found in the General Statutes (G.S.) and Communicable Disease rules.

1. General Statute 130A-144

   a. Provides the authority for the local health director to investigate all cases of communicable diseases or conditions;
   b. Calls for the adoption of rules that prescribe control measures for communicable diseases and conditions; and
   c. Requires that all persons comply with control measures, including submission to examinations and tests.

2. General Statute 130A-145 gives quarantine and isolation authority to the State Health Director and local health directors.

3. General Statute 130A-25 states it is a misdemeanor to violate G.S. 130A-144(f) or G.S. 130-145 and specifically states that a person convicted of violating either of these General Statutes shall be sentenced for no more than two years and may not be released prior to the two years unless the District Court determines that release would not endanger the public health.

4. Communicable Disease rules found in 10A NCAC 41A .0205 Control Measures -Tuberculosis provide requirements for the control of tuberculosis, including American Thoracic Society references for the diagnosis and treatment of TB.

Q. Incarceration Procedure

1. Isolation Orders:

a. **"Isolation"** means the authority to limit the freedom of movement **or actions** of a person with a communicable disease or communicable condition for the period of communicability to prevent the direct or indirect conveyance of the infectious agent from the person to other persons who are susceptible or who may spread the agent to others.

b. An Isolation Order may:
- require the person to comply with control measures, i.e., treatment orders, diagnostic tests, laboratory tests, etc.;
- If the order includes the requirement to remain in the home until the TB nurse advises that they are no longer infectious, then the initial order is limited to 30 days. The order can be extended by the court for up to one calendar year at a time if the court determines that such extension is reasonably necessary based on a petition to the court by the health director or designee. The extension should be sought at least three working days before the previous order expires. **(see GS 130A-145(d), amended June, 2004).**

c. The health director issues a written Isolation Order **(see sample order at the end of this chapter)** as soon as non-compliance is exhibited. The Isolation Order must specify the following:
- Current disease status;
- Required control measures and exactly how the patient is to comply with these measures;
- Statutory authority for the Isolation Order and required control measures; and
- Statutory basis and legal steps to be taken if patient fails to comply with the Isolation Order.

d. The health director or designee should confer with the county attorney, judge, district attorney, and public defender regarding legal steps if the Isolation Order is violated.

e. To assure immediate sentencing, a public defender must be assigned to the Health Law Violator (HLV) as soon as the HLV arrest warrant is issued.

f. A HLV sent to the Department of Corrections (DOC) prior to sentencing is considered a "safe keeper" until trial and sentencing. The county will be charged a per diem fee for each day the HLV remains in safe-keeper status. Central Prison and N.C. Correctional Institution for

Women in Raleigh are the facilities used for safe keepers if the sheriff does not believe the jail can adequately provide for the HLV.

g. If the patient cannot be located to issue an Isolation Order, an arrest warrant should be initiated.

2. Arrest Procedure:

a. The health director, his/her designee and/or the county attorney requests magistrate to swear out arrest warrant.

b. Sheriff's department arrests HLV.

c. If convicted, the HLV is sentenced **"for duration of tuberculosis disease treatment or up to two (2) years"** as determined in accordance with GS 130A-25(c).

d. The local sheriff's department notifies Department of Corrections (DOC)of the impending arrival of the HLV by calling:

- Advise DOC that this is a high priority transfer, the person to be transferred is a HLV and cannot go by inmate transfer van.
- Advise DOC if masks are needed when transferring HLV to prison.
- After contacting Transfer Coordinator, contact the Infection Control Coordinator for the N.C. Division of Prisons (919-838-3865) and provide the same information.

e. The local health department should contact the Infection Control or TB nurse at the receiving facility and arrange to fax all pertinent medical information before the HLV arrives and then send copies of medical information and chest x-rays with the HLV.

3. DOC Medical Management

a. **Male** non-infectious HLVs needing minimum security are sent to
Hoke Correctional Institution
Mailing address:
P.O. Box 700
Raeford, NC 28376

Street address:
Old Hwy 211
McCain, NC 28361
Phone (910) 944 -7612 Fax (910) 944-4752

Male infectious HLV's are sent to Central Prison in Raleigh. Infection Control Nurse 919-733-0800

b. **Female** HLVs are sent to N.C. Correctional Institution for Women (NCCIW). For patient information, contact Infection Control Nurse at:
N.C. Correctional Center for Women

1034 Bragg Street
Raleigh N.C. 27610
(919) 733 - 4340 Ext. 323

c. Obtain copies of TB infection or disease treatment medical records for **released** inmates by sending a Release of Information to:

Medical Records Manager, DOP Health Services
2405 Alwin Ct, Raleigh, N.C. 27699-4268
Telephone: (919) 715-1570 or 919-715-1584
Fax: 919-715-1581

4. DOC Health Law Violator Release from Prison Procedure **(see sample letter X 2. at the end of chapter)**:

a. The prison unit attending physician and the State TB Nurse consultant will examine the patient's record to determine that treatment has been completed prior to issuance of a release letter.

b. Upon determining that TB treatment has completed, the prison unit physician will send a letter (addressed to the county Health Director), to N.C. TB Control for the state TB Medical Director's signature. The letter will state the completion date and recommendation for release. A Community TB Referral (DC516), copies of all TB drugs received, most recent lab work, and end of treatment chest film (If applicable) will be attached to the letter to document treatment received.

5. State Health Law Violator Release Letter Procedure

a. Upon receipt of the letter and accompanying documentation from the prison unit physician, the State Health Director through N.C. TB Control will submit a letter concurring with the attending physician's recommendations for release.

b. Both letters will be sent to the county health director from N.C. TB Control.

6. Local Health Department Health Law Violator Release from Prison Procedure

a. Upon receipt of the letters and the accompanying documentation from the prison's attending physician, the county health director will review the case with the local TB clinician. The Community TB Referral (DC 516) and copies of all TB drugs received, most recent lab work, and end of treatment chest film (if applicable) will be attached to the letter documenting the completed treatment regimen.

b. The health director will prepare a similar letter addressed to the district court judge and advise the county attorney and district attorney of release request. All three letters will be hand-carried to district court to request release of the HLV (See sample letter X 1. at the end of this chapter.).

c. The district court judge will review the case and make a determination regarding an order for the HLV release.

d. The court order for release is sent to the N.C. DOC Department of Combined Records:

Manager, Combined Records
2020 Yonkers Road
4226 Mail Service Center
Raleigh, NC 27699-4226
Phone: 919-716-3200 Fax 919-716-3963

R. Sample TB Treatment Agreement

TB TREATMENT AGREEMENT

Patient Name: _____ DOB _____ Date: _____

Patient Address: _____ Health Department: _____

I, _____, understand I have suspected or confirmed tuberculosis and have been prescribed by a physician to treat this disease. If my disease goes untreated, there may be serious results:

- my illness may last longer or become more severe.
- I may spread TB to others.
- I may develop and spread drug-resistant TB.
- I can die from TB.

The _____County Health Department has the responsibility of being sure I complete treatment for my tuberculosis and do not give tuberculosis to others. To help me complete TB treatment, the health department will:

- supply all my TB medications, x-rays, and laboratory testing free of charge.
- discuss with a physician any problems relating to my disease.
- observe me take each dose of medicine.
- see me at least monthly to evaluate for any side effects to my TB medications.

To complete my treatment and protect my family, friends and co-workers I will:

- give sputum samples when asked.
- keep all appointments for medical testing and x-rays.
- be at the agreed-upon location to take my TB medication.
- tell the health care worker whenever I plan to change my address or location.

Visit Day(s): _____ Time: _____ Location: _____

If a scheduled visit falls on a holiday, the health care worker will work with me to make an adjustment in my schedule.

I have read this agreement and understand the following **(initial on line**):

_____ Taking TB medication is very important.

_____ I am responsible for the four tasks listed above.

_____ I have been told to stop taking my medication and call my doctor and the health department if I have any side effects.

_____ If I fail to complete these tasks, legal action can be taken to make sure I complete my TB treatment.

_____ I have been given the North Carolina TB Control program's pamphlet, "TB and You" which lists the possible side effects of tuberculosis medicines. These possible side effects have been explained to me. I will inform the TB nurse of any problems that I may have regarding any physical complaint or possible side effects to the tuberculosis medications.

_____ _____

Patient Signature and Date Witness Signature and Date

S. Sample TB Treatment Agreement (Spanish)

COMPROMISO DE TRATAMIENTO DE TUBERCULOSIS

Nombre del paciente: _____ Fecha de nacimiento _____
Fecha de hoy: _____

Dirección del paciente: _____ Departamento de Salud: _____

Yo, _____, entiendo que se sospecha o se ha confirmado que tengo tuberculosis, y que un médico me ha recetado medicamentos para tratar esta enfermedad. Si no se trata mi enfermedad, esto puede ocasionar graves resultados:

- mi enfermedad puede prolongarse más o agravarse
- puedo contagiar la tuberculosis a otras personas
- puedo desarrollar una tuberculosis resistente a los medicamentos y contagiar esta a otros
- puedo fallecer por causa de la tuberculosis

El Departamento de Salud del condado _____ es responsable por asegurarse de que yo complete mi tratamiento contra la tuberculosis y de que no contagie la tuberculosis a otras personas. A fin de ayudarme a completar mi tratamiento contra la tuberculosis, el Departamento de Salud:

- me proporcionará todos los medicamentos contra la tuberculosis, las radiografías y los análisis clínicos en forma gratuita
- consultará con un médico todos los problemas relacionados con mi enfermedad
- me observará tomar todas las dosis de medicamentos
- me verá por lo menos una vez al mes para evaluarme en cuanto a cualquier efecto secundario de los medicamentos contra la tuberculosis

A fin de completar mi tratamiento y proteger a mi familia, mis amistades y mis compañeros de trabajo, yo:

- entregaré las muestras de esputo cuando me lo soliciten
- acudiré a todas las citas para los exámenes médicos y las radiografías
- me presentaré en el lugar acordado para tomar mis medicamentos contra la tuberculosis
- informaré al trabajador de salud cada vez que piense cambiar de domicilio o de localidad

Día(s) de visita: _____ Hora: _____ Lugar: _____

Si una visita programada cae en día festivo, el trabajador de salud coordinará conmigo para hacer un ajuste en mi programa de medicamentos.

He leído este compromiso y entiendo lo siguiente (**Escriba sus iniciales sobre cada una de las líneas**.)

_____ Es muy importante que yo tome los medicamentos contra la tuberculosis.

_____ Soy responsable por realizar las cuatro tareas indicadas anteriormente.

_____ Se me ha indicado que deje de tomar los medicamentos y llame a mi médico y al departamento de salud si tengo algún efecto secundario.

_____ Si no cumplo con realizar esas tareas, puede tomarse una acción legal en mi contra para asegurar que complete mi tratamiento contra la tuberculosis.

_____ Me han entregado el panfleto «La tuberculosis y usted» del Programa de Control de la Tuberculosis de Carolina del Norte, el cual indica los posibles efectos secundarios de los medicamentos contra la tuberculosis. Se me han explicado los posibles efectos secundarios. Informaré a la enfermera de tuberculosis acerca de cualquier problema que tenga que esté relacionado con malestar físico o con posibles efectos secundarios de los medicamentos contra la tuberculosis.

_____ Firma del paciente y fecha

_____ Firma del testigo y fecha

T. Sample Isolation Order for TB Control

(Health Department Letterhead)

ISOLATION ORDER FOR TB CONTROL

I, _____, Health Director of the _____ County Health Department, pursuant to authority vested in me by General Statute 130A-145, issue this Isolation Order for TB Control to

_____(patient name)

DOB: _____

You are suspected of having or confirmed to have tuberculosis disease based on diagnostic evaluation that may include history of present illness, tuberculin skin testing or interferon gamma release assay testing, radiographic findings or laboratory findings.

You have been properly informed and counseled by _____ RN, TB Control Nurse with the_____ County Health Department regarding the control measures for tuberculosis disease. Failure to comply with the prescribed control measures will violate N.C. General Statute 130A-144.

You are ordered to comply with the following control measures:

-
-
-
-
-

If you fail to comply with this Isolation Order for TB Control, you will be subject to prosecution for a misdemeanor offense pursuant to N.C. General Statute 130A-25 (a) and (b), punishable by up to two (2) years imprisonment, as determined in accordance with N.C. General Statute 130A-25 (c).

If you move to a new address or leave this county, you are required to notify this Health Department.

The staff of this Health Department remains available to provide assistance and counseling to you concerning your tuberculosis disease and compliance with this Isolation Order for TB Control.

_____

Health Director Date

Issued by: _____

I have received the original copy of this order: _____

Patient

I witnessed this issuance: _____

U. Sample Isolation Order for TB Control (Spanish)
(Health Department Letterhead)

Orden de Aislamiento para el Control de la Tuberculosis
Isolation Order for TB Control

Yo, _____ , el director de salud del condado de _____ de acuerdo a la autoridad depositada en mí por los *Estatutos Generales de Carolina del Norte* (130A145), expido esta *Orden de Aislamiento* a _____ (patient name)

Fecha de Nacimiento: _____

Se sospecha o se ha confirmado que usted padece de tuberculosis basándonos en un diagnóstico que puede incluir su historia clínica, la prueba de tuberculina, radiografías o pruebas de laboratorio.

Usted ha sido informado y aconsejado por (name) _____ (title) _____ (agencia) _____ respecto a las medidas de control que se necesitan tomar para el control de la tuberculosis. El no cumplir con las medidas de control violará as leyes de los *Estatutos Generales de Carolina del Norte* (130A-144) l

Se le ordena a usted el cumplir con las siguientes medidas de control:

-
-
-
-
-

Si usted no acata esta *Orden de Aislamiento* para el control de la tuberculosis, usted pudiera ser acusado de un crimen menor, de acuerdo a los *Estatutos Generales de Carolina del Norte* (130A-25), y podría ser condenado a encarcelamiento hasta por dos años.

Si usted se cambia de dirección o se va de este condado, NOTIFIQUE de este cambio al Departamento de Salud.

El personal de este Departamento de Salud está disponible para ayudarle y aconsejarle en todo lo relacionado con la tuberculosis, y cómo cumplir adecuadamente con esta *Orden de Aislamiento*.

_____ _____
Director de Salud Fecha

Expedida por: _____ _____
Fecha

Recibí el original de esta orden: _____ _____
Paciente Fecha

V. Sample Isolation Order to Limit Freedom of Movement and Access

(Health Department Letterhead)

TB ISOLATION ORDER TO LIMIT FREEDOM OF MOVEMENT AND ACCESS

I, _____, Health Director of the _____ County Health Department, pursuant to authority vested in me by N.C. General Statute 130A-145, issue this Isolation Order to _____(patient name).

DOB: _____

You are reasonably suspected of having or confirmed to have tuberculosis disease based on diagnostic evaluation that may include history of present illness, tuberculin skin testing or interferon gamma release assay testing, radiographic findings or laboratory findings.

You have been properly informed and counseled by (name)_____, (title)_____, (agency)_____, regarding the control measures for tuberculosis disease. Failure to comply with the prescribed measures will violate N.C. General Statute 130A-144.

You are ordered to comply with the following control measures:

- You must remain in your home, and not allow access by anyone other than those who reside in the household and your health care providers, until the Health Department advises you that you are no longer infectious and are no longer restricted to the house. **(This statement can be modified if needed to address specific circumstances.)**
-
-
-
-
-

If you fail to comply with this TB Isolation Order to Limit Freedom of Movement and Access, you will be subject to prosecution for a misdemeanor offense pursuant to N.C. General Statute 130A-25 (a) and (b), punishable by up to two (2) years imprisonment, as determined in accordance with N.C. General Statute 130A-25 (c).

If you move to a new address or leave this county, you are required to notify this Health Department.

The staff of this Health Department remains available to provide assistance and counseling to you concerning your tuberculosis disease and compliance with this TB Isolation Order to Limit Freedom of Movement and Access.

Pursuant to N.C. General Statute 130A-145 (d), you may petition the superior court for review of this TB Isolation Order to Limit Freedom of Movement and Access. N.C. General Statute 130A-145 (d) states in part: "Any person substantially affected by that limitation may institute in superior court in Wake County or in the county in which the limitation is imposed an action to review that limitation. The official who exercises the quarantine or isolation authority shall give the persons known by the official to be substantially affected by the limitation reasonable notice under the circumstances of the right to institute an action to review the limitation. If a person or a person's representative requests a hearing,

the hearing shall be held within 72 hours of the filing of that request, excluding Saturdays and Sundays. The person substantially affected by that limitation is entitled to be represented by counsel of the person's own choice or if the person is indigent, the person shall be represented by counsel appointed in accordance with Article 36 of Chapter 7A of the General Statutes and the rules adopted by the Office of Indigent Defense Services."

The authority of this TB Isolation Order to Limit Freedom of Movement and Access to limit your freedom of movement and access expires in 30 days unless extended or modified by a court pursuant to G.S. 130-145.

_____ _____

Health Director Date

Issued by: _____ _____

Date

I have received the original copy of this order: _____ _____

Patient Date

W. Sample Isolation Order to Limit Freedom of Movement and Access (Spanish) (Health Department Letterhead)

TUBERCULOSIS
Orden de Aislamiento para Limitar Libertad de Movimiento y Acceso
TB Isolation to Limit Freedom of Movement and Access

Yo, _____ , el director de salud del condado de _____ de acuerdo a la autoridad depositada en mí por los *Estatutos Generales de Carolina del Norte* (130A145), expido esta *Orden de Aislamiento* a _____ (patient name)

Fecha de Nacimiento: _____

Se sospecha o se ha confirmado que usted padece de tuberculosis basándonos en un diagnóstico que puede incluir su historia clínica, la prueba de tuberculina, radiografías o pruebas de laboratorio.

Usted ha sido informado y aconsejado por (name) _____
(title) _____ (agency) _____ respecto a las medidas de control que se necesitan tomar para el control de la tuberculosis. El no cumplir con las medidas de control prescritas violará las leyes de *Estatutos Generales de Carolina del Norte* (130A-144)

Se le ordena a usted el cumplir con las siguientes medidas de control:

- Usted debe permanecer en su hogar y no permitir acceso a otras personas, a excepción de aquellas que viven en su hogar y a las personas que le proporcionan los servicios de salud, hasta que el *Departamento de Salud* le informe que ya no hay peligro de infección y que no tiene que estar aislado en su casa.
  (This statement can be modified if needed to address specific circumstances)
-
-
-
-

Si usted no acata esta *Orden de Aislamiento para limitar su libertad de movimiento y acceso*, usted pudiera ser acusado de un crimen menor, de acuerdo a los *Estatutos Generales de Carolina del Norte* (130A-25), y podría ser condenado a encarcelamiento hasta por dos años, tal como está determinado por los *Estatutos Generales de Carolina del Norte* (130ª-25).

Si usted se cambia de dirección o se va de este condado, se requiere que NOTIFIQUE de este cambio al Departamento de Salud.

El personal de este Departamento de Salud está disponible para ayudarle y aconsejarle en todo lo relacionado con la tuberculosis, y cómo cumplir adecuadamente con esta *Orden de Aislamiento*.

De acuerdo a los *Estatutos Generales de Carolina del Norte,* usted puede pedir a una corte superior una revisión de esta *Orden de Aislamiento para Limitar Libertad de Movimiento y Acceso*. Los *Estatutos Generales de Carolina del Norte* dicen que: “Cualquier persona que es afectada substancialmente por la limitación, puede pedir a la corte superior del condado de Wake, o en el condado donde la limitación es ordenada, que se revise la limitación impuesta. El oficial que ordenó el aislamiento o cuarentena deberá dar a las personas afectadas un aviso de cómo pueden pedir esta revisión. Si alguna persona pide una audiencia, la audiencia deberá tener lugar dentro de un periodo de 72 horas (excluyendo sábados y domingos). La persona sustancialmente afectada por la

limitación, tiene derecho a ser representada por algún abogado de su elección, o si la persona es indigente, la persona pudiera ser representada por un abogado de oficio, tal como lo establece el Artículo 36 del Capítulo 7ª de los *Estatutos Generales* y las reglas adoptadas por la *Oficina de Servicios de Defensa del Indigente".*

La validez de esta *Orden de Aislamiento para Limitar Libertad de Movimiento y Acceso*, expira en un periodo de 30 días, a menos que sea extendida o modificada por la corte, de acuerdo a los *Estatutos Generales* (130-145).

_____ _____
Director de Salud Fecha

Expedido por: _____ _____
Fecha

Recibí el original de esta orden: _____ _____
Paciente Fecha

X1. **Health Department**: Sample Release Letter

Dear (**District Court Judge's** name):

Pursuant to NC GS 130A-25 (c), (Violator's name) will have completed the prescribed course of therapy for tuberculosis disease on (date). Appropriate laboratory tests confirm that she/he is no longer a danger to the public health. I have received consultation from the State Health Director, the prison unit physician and the TB Medical Consultant of the confinement facility (see attached). Therefore, I recommend that an order for his/her release be issued to be effective on (date - same date listed above).

Sincerely,

(Health Director's name), Director

(_____) County Health Department

Attachments

cc: Medical Director, Department of Corrections
McCain Correctional Hospital or North Carolina Correctional Center for Women or Central Prison

X2. **DOC:** Sample Release Letter

Dear (**Local Health Director** of Violator's home county):

Pursuant to North Carolina General Statute 130A-25(c), (Violators name) has completed the prescribed course of therapy for tuberculosis disease on (date of last dose of medicine). Appropriate laboratory tests confirm that he/she is no longer a danger to the public health. Therefore, I recommend that you petition the District Court requesting an order for his/her release to be effective (date).

Enclosed please find a copy of his/her latest chest radiograph, laboratory reports, and medication records.

Sincerely,

_____ _____
Attending physician (prison) TB Medical Director, State of NC

CC: State Health Director
Director of Health Services, DOC
Nurse Consultant, State of NC
County TB Nurse

Y. Community TB Referral - NC Dept. of Corrections

(this referral is sent to the health departments for all inmates being treated for LTBI or disease at the time of release from prison)

North Carolina Department of Public Safety Community TB Referral

*Complete this form and forward copy to the local health department in county where inmate is to be released **14** days prior to release.*

1. PPD Skin Test Date: _____ Result: _____

2. Chest X-ray (attach copy of report) _____ Within Normal Limits _____ Abnormal

3. LFT (attach copy of report) _____ (Date) First _____ (Date) Last

Patient's wgt. _____ lb. Date: _____

4. HIV test results _____ (Date)

5. TB Medication: (attach copy of physician's order for medications and **ALL** applicable MARs for duration of treatment while in the custody of DPS.)

Drug	Dosage	Start Date	Route	How Often	End Date	Special Instructions
___Isoniazid						
___Rifampin						
___Pyrazinamide						
___Ethambutol						
___Pyridoxine						
___Rifapentine						
___Other Rx						
___Other Specify						

TO: _____ (County / District Health Dept) FROM: _____ (Prison Name and Number)

_____ (Address)

Telephone #_____

RE: Patient Name: _____ Birth Date: _____
Race: _____ Sex: _____ Social Security #: _____ Inmate#: _____
Address: _____

The above named individual has been instructed to follow-up with the Health Department TB Program. The above information extracted from Division of Prisons medical records.

Completed By: _____ Title: _____ Date: _____
Date Sent: _____ Mailed: _____ Faxed: _____

This form is not to be amended, revised or altered without approval of the Medical Records Committee.

File: Section II of Outpatient Health Record
Miscellance of Inpatient Record

DC-516 (revised 8/13)

PRINT

Inmate Name: _____

Inmate Number: _____

Facility Name: _____

1

Inmate Name: _____ Inmate Number: _____

Complete for Active Disease Only

Acid Fast Bacteriology

Date Submitted	Type of Specimen	Smear Results	Date Reported	Culture Results	Date Reported	Sensitivity	Follow-up Instruction

T.B. Medication Active Treatment _____ Reason not Started_____
Preventive _____

Date Started	Unit	Drug	Dosage	Freq.	Route	Date Stopped	Reason Stopped

Chest X-rays

Date	Position	Results

LFT (other)

Date	Test	Normal	Abnormal	Comments

Z. First-Line TB Drugs

Drug	Doses in mg/kg **(Maximum Dose) is listed in parenthesis**					
	Daily		Twice or thrice weekly		Once weekly	
	Children (<15 years)	**Adults**	**Children (<15 years)**	**Adults**	**Children ages 2-14**	**Adults**
INH	10 - 15 (300mg)	5 (300mg)	20 - 30 (900mg)	15 (900mg)	20 (900)	15 (900)
RIF	15 - 20 (600mg)	10 (600mg)	15 - 20 (600mg)	10 (600mg)	xxxx	xxxx
RBT Rifabutin	5 (300 mg)	5 (300 mg)	5 (300 mg)	5 (300 mg)	xxxx	xxxx
RPT Rifapentine	**XXXXXX**	**XXXXXXXX**	**XXXXXXX**	10 **once wkly** (900 mg)	20 (900	20 (900)
PZA	30-40 mg (2000 mg) Round up to the next available dose	See Suggested doses in table below	50 (4000 mg)	See Suggested doses in table below	xxxxxxxxxx	
EMB	20 mg (2500mg) round up to the next available dose	See Suggested doses in table below	50 (2500 mg)	See Suggested doses in table below	xxxxxxxxxx	

AA. **The following guidelines‡ should be used to determine the appropriate dosing for PZA and EMB in adults:**

Suggested **pyrazinamide** doses, using whole tablets, for adults weighing 40-90 kg

Weight in kg (estimated lean body wt)	**40 - 55 kg (88 to 121 lbs)**	**56 - 75 kg (123 to 165 lbs)**	**76 - 90 kg (167 to 198 lbs)**
Daily, mg (mg/kg)	1000 (18.2 - 25)	1500 (20.0 - 26.8)	2000[1] (22.2 - 26.3)
Twice weekly, mg (mg/kg)	2000 (36.4 - 50.0)	3000 (40 - 53.6)	4000[1] (44.4 - 52.6)
Thrice weekly, mg, (mg/kg)	1500 (27.3 - 37.5)	2500 (33.3 - 44.6)	3000[1] (33.3 - 39.5)

[1] Maximum dose regardless of weight

Suggested **ethambutol** doses, using whole tablets, for adults weighing 40-90 kg

Weight in kg (estimated lean body wt)	**40 - 55 kg (88 to 121 lbs)**	**56 - 75 kg (123 to 165 lbs)**	**76 - 90 kg (167 to 198 lbs)**
Daily, mg (mg/kg)	800 (14.5 - 20.0)	1200 (16.0 - 21.4)	1600[1] (17.8 - 21.1)
Twice weekly, mg (mg/kg)	2000 (36.4 - 50.0)	2800 (37.3 - 50.0)	4000[1] (44.4 - 52.6)
Thrice weekly, mg (mg/kg)	1200 (16.0 - 21.4)	2000 (26.7 - 35/7)	2400[1] (26.7 - 31.6)

[1] Maximum dose regardless of weight

‡ Nahid P et al, Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Disease Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. Clinical Infectious Diseases 2016; 63(7): e147-195..

BB. Common Adverse Reactions to First-Line Drugs

Adverse Reactions	Signs and Symptoms	Lab Test	Usual Causes
Dermatitis	pruritus, rash, hives, fever		PZA ,RIF, INH, rarely EMB
Hepatitis	anorexia, nausea, vomiting, fatigue, dark urine, jaundice	ALT, AST, Bilirubin	INH, RIF, PZA, rarely EMB
GI upset	anorexia, nausea, vomiting, epigastric pain		PZA, RIF
Peripheral neuropathy	numbness or paresthesias of feet and hands		INH
Joint signs and symptoms	pain, swelling, tenderness, heat, redness	Uric Acid	PZA, RIF
Renal signs and symptoms	hematuria, uremia	Serum Creatinine	RIF
Hematologic manifestations	leukopenia, thrombocytopenia	CBC with platelets	RIF, INH, PZA, RBT, EMB
Uveitis	inflammation of the iris, choroid and sub-scleral layer of the eye		RBT
Optic neuritis	decrease in vision and/or loss, color blindness		EMB

See Chapter VI for drug interactions between TB medications and other drugs

For more information about adverse reactions and drug interactions for 1st and 2nd line tuberculosis drugs, see Nahid P et al, Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Disease Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. Clinical Infectious Diseases 2016; 63(7): e147-195.This document is available on line at http://cid.oxfordjournals.org/content/63/7/e147.

CC Basic Components of TB Disease Management

- Initial diagnostic evaluation of IGRA/TST, chest x-ray, bacteriology, and clinical assessment indicate active TB disease and **INH, RIF, PZA, & EMB** treatment has been initiated.
- **Directly Observed Therapy is the standard of care for the treatment of disease and is required by law in North Carolina.**
- MD orders must specify daily and twice/thrice weekly dosages and the duration of each drug.
- The initial clinical assessment should include a listing of all other medical conditions and medications, as well as information about other providers involved in the patient's medical care (particularly the primary care provider). For example, a patient with TB and diabetes should have, at a minimum, the following data collected:
  - Primary care provider name and contact information (if patient has a primary care physician)
  - Most recent hemoglobin A1c value and date collected
  - List of known complications of diabetes (nephropathy, retinopathy, neuropathy)
- Patients with medical conditions besides TB who do not have an identified primary care provider should be assisted to find a primary care provider early in TB treatment
- Regular communication with other providers involved in the patients' care is an important aspect of TB disease management. At a minimum, communication with the primary care provider should occur at the beginning and end of TB treatment.

Weeks of Therapy	Clinical Assess-ment	Sputum	Chest x-ray	IGRA/ TST	Hepatic Function Panel >15 y/o	CBC >15 y/o	Creat-inine	Vision while on EMB	Home Visit	TST/IGRA Con-tacts	HIV
Baseline	x	x	x	x	x	x	x	x			x
1 week	x								x	x	
2 weeks		x									
4 weeks	x	x						x			
6 weeks		x									
8 weeks	x	x	x*					x		x**	
10 weeks		x									
12 weeks	x	x									
13 - 26 weeks	x document at least monthly										
26 weeks Therapy Complete	Close record		@ 2 weeks before end of therapy								

The ordered amounts of all TB medications are to be ingested in a SINGLE DOSE, according to the prescribed schedule.

Collect sputums every two weeks until culture negative. 85 percent of cases with fully susceptible Mtb should culture convert within two months of starting the INH, RIF, PZA, EMB regimen.

*Obtain a chest x-ray after two months of treatment for pulmonary disease if pretreatment pulmonary culture results are negative.

A hepatic function panel should be obtained any time symptoms suggest hepatotoxicity. **Stop meds and notify MD** if nausea, vomiting, anorexia, rash, lethargy, fatigue, pruritus, dark urine, or jaundice occur **OR** if lab work is abnormal.

** A second IGRA/TST is indicated for IGRA/TST negative **close** contacts to **infectious** TB disease.

DD. International Classification System for Tuberculosis

CLASS	TYPE	DESCRIPTION
0	No TB exposure Not infected	No history of exposure Negative reaction to TST **or** Negative IGRA test results
1	TB exposure No evidence of infection	History of exposure Negative reaction to TST **or** Negative IGRA test results
2	TB infection No disease	Positive reaction to TST **or** Positive IGRA test results Negative bacteriologic studies (if done) No clinical or radiographic evidence of TB
3	Current TB disease	M. tuberculosis culture (if done) or Positive reaction to TST **or** Positive IGRA test results and Clinical or radiographic evidence of current disease
4	Previous TB disease	History of episode (s) of TB Or Abnormal but stable radiographic findings Positive reactions to the TST **or** Positive IGRA test results Negative bacteriologic studies (if done) And No clinical or radiographic evidence of current disease
5	TB Suspect	Diagnosis Pending

EE. Tool for Reporting Suspected or Confirmed TB Cases to TB Nurse Consultant Within 7 Days of Notification

Date Report Faxed/Called _____Date Suspect reported to county _____
County _____ Nurse _____
Patient's Name:_____ Gender_____ Race_____
Address:_____
DOB:_____
AFB Smear results:_____ Culture Results: _____
Specimen Source/Collection Date _____Pulmonary ____Extra-pulmonary_____
PPD results:_____ IGRA results:_____
HIV status_____ Date tested_____
Chest x-ray results:_____
_____

Drugs/Dosages: Date started: _____ Weight _____

INH _____mg	Daily _____	Bi-weekly _____
Rifampin _____mg	Daily _____	Bi-weekly _____
PZA _____mg	Daily _____	Bi-weekly _____
EMB _____mg	Daily _____	Bi-weekly _____
Other _____mg	Daily _____	Bi-weekly _____

Medical or Population Risk Factors:
_____
_____

Potential Drug Interactions:
_____
_____

Symptoms and Duration:
_____
_____
_____

Contact Investigation Status (describe progress of CI, and areas of high risk, such as, children, nursing homes, schools, HIV positive contacts, etc); indicate if no contact identified
_____
_____
_____

Have baseline labs been drawn? Yes ____ No ____

If HIV+: CD4 level _____ Date of most recent test_____
If diabetic: HbA1c (date):_____

Additional Comments:
_____
_____
_____

FF. Sample Standing Orders for Suspect/Confirmed TB Cases

Sample Standing Order Example: Suspect or Known Tuberculosis

Assessment: All PHN's employed or contracted by the agency that have completed a TB program orientation and have been appropriately trained in agency protocols shall evaluate for signs and symptoms of tuberculosis and obtain tests. The PHN will initiate this standing order if a patient reports or the medical record indicates he/she has two or more findings listed under subjective and objective.

1. **Subjective Findings:**
   a. Night sweats;
   b. Shortness of breath;
   c. Chest pain;
   d. Appetite loss; and/or
   e. Unexplained fatigue.
   f. Unexplained productive cough for greater than three weeks;
   g. Hemoptysis;
   h. Unexplained weight loss;
   i. Unexplained fever;

2. **Objective findings**:
   a. Positive tuberculin skin test or Positive IGRA;
   b. Abnormal chest x-ray, indicated by a TB clinician and/or radiologist.
   c. Positive acid-fast bacillus (AFB) smear.

Plan of Care:

1. Implementation:
   a. Place a tuberculin skin test (TST) or draw blood for an IGRA (Interferon Gamma Release Assay) unless there is a documented previous positive TST or IGRA.
   b. Obtain three natural or induced sputum specimens on three consecutive days, preferably early morning specimens, and send for AFB smear, culture, and susceptibility.
   c. Continue obtaining two sputum specimens for AFB smear and culture every two weeks until there are two consecutive negative sputum culture results reported.
   d. Obtain a posterior-anterior (PA) chest x-ray on persons $\geq$ 5 years of age.
   e. Obtain both a PA and lateral view on children under the age of 5 years.
   f. Obtain an HIV test and if the individual is $\geq$ 15 years old also obtain the following:
      i. Liver function panel;
      ii. Serum creatinine; and
      iii. CBC with differential (platelets).
   g. If during TB treatment the patient complains of signs and symptoms consistent with hepatotoxicity, such as nausea, vomiting, loss of appetite, dark (tea or cola colored) urine, malaise, abdominal discomfort, or yellow skin or sclera, hold TB medications, and draw hepatic function panel.
   h. If during the treatment the patient reports signs and/or symptoms of immunologic reactions such as fever, easy bleeding or bruising, or low hemoglobin (< 13.5 for men, < 12.5 for women, and < 11 for children (between 5 years but less than 15 years), draw CBC with platelets and consult physician.
   i. Obtain hepatic function panel monthly for the following individuals:
      i. Has abnormal baseline hepatic function;
      ii. Pregnant or up to three months postpartum;

iii. Those with symptoms of hepatotoxicity;
iv. Persons taking potentially hepatotoxic drugs;
v. Persons with chronic active hepatitis B or C;
vi. Persons who report any alcohol intake while taking TB medications;
vii. Persons with HIV infection.

2. Nursing Action:

a. Review with, and have the patient sign the TB Treatment Agreement if TB treatment is ordered.
b. Ensure that there is documentation of an exam by a physician or mid- level provider within the first four weeks of initiation of TB therapy.
c. Ensure that physician reviews laboratory results and documents this per the agency policy on reviewing laboratory results. (Agency should list the name of this policy here)

3. Criteria for Calling the Physician:

a. If the patient develops side effects from the medications such as, nausea, vomiting, loss of appetite, dark urine, jaundice, malaise, abdominal discomfort, skin rash, fever, easy bleeding or bruising, or low hemoglobin (< 13.5 for men, < 12.5 for women, and < 11 for children (between 5 years but less than 15 years) occur.
b. If the patient becomes pregnant.
c. Anytime laboratory results are abnormal.
d. If additional orders are needed.
e. If drug resistance is reported.
f. If sputum cultures are still positive after taking TB medications for eight weeks.
g. If the patient's clinical condition worsens.
h. If there is any question about whether to carry out the standing order call the physician.

4. Follow-up:

a. Follow-up with the physician for treatment orders after initial evaluation is complete.
b. Evaluate the patient monthly using the Tuberculosis Flow Sheet (DHHS 2810).
c. Recalculate medication dosage monthly after weighing.
d. Ensure that there is documentation of an exam by a physician or mid- level provider within the last four weeks of TB therapy.
e. Obtain end of treatment chest x-ray if the patient has pleural or pulmonary TB.

Resources: NC TB Control Program Policy Manual 2012 edition.

Legal Authority: Nurse Practice Act, G.S. 90-171.20 (7) (f) & (8) (c)

Date written: _____

Approved by: _____ Date: _____

Approved by: _____ Date: _____

Approved by: _____ Date: _____